

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
21 April 2005 (21.04.2005)

PCT

(10) International Publication Number
WO 2005/035050 A1

(51) International Patent Classification⁷: A61N 1/08,
A61B 5/103, 5/11, A61N 1/37

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(21) International Application Number:
PCT/US2004/002113

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(22) International Filing Date: 26 January 2004 (26.01.2004)

(81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/503,218 15 September 2003 (15.09.2003) US
10/691,917 23 October 2003 (23.10.2003) US

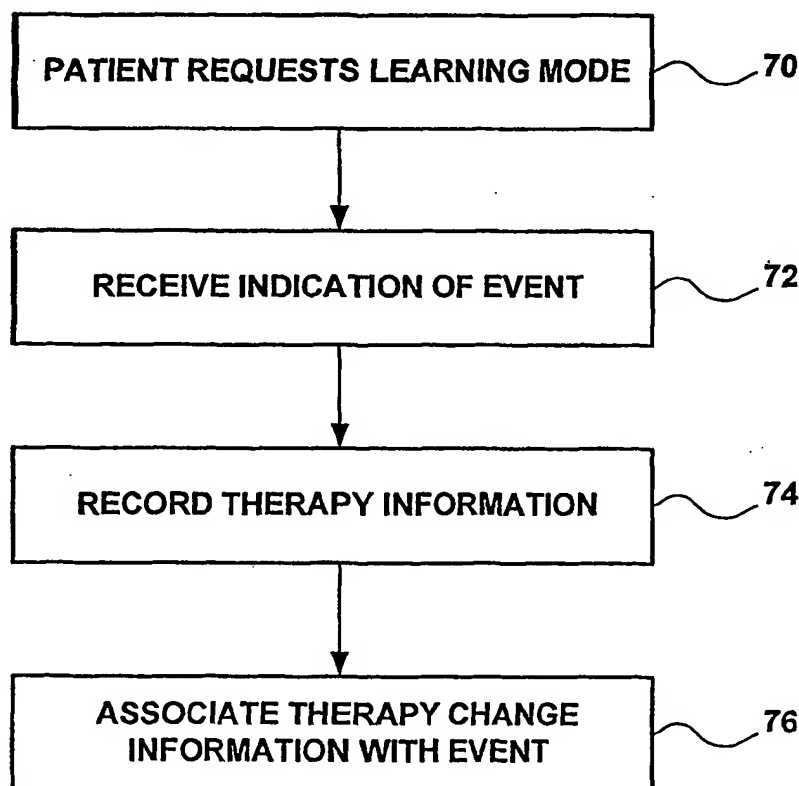
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(84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), Euro-
pean (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR,
GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK,

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[Continued on next page]

(54) Title: AUTOMATIC THERAPY ADJUSTMENTS



(57) Abstract: A medical device detects a previously defined event, and controls delivery of therapy to a patient according to therapy information associated with the previously defined event. In exemplary embodiments, the medical device enters a learning mode in response to a command received from a user, e.g., the patient or a clinician. In such embodiments, the medical device defines the event, collects the therapy information, and associates the therapy information with the defined event while operating in the learning mode. In some embodiments, the medical device defines the event based on the output of a sensor that indicates a physiological parameter of the patient during the learning mode. The sensor may be an accelerometer, which generates an output that reflects motion and/or posture of the patient. The medical device may collect therapy information by recording therapy changes made by the user during the learning mode.



WO 2005/035050 A1



TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

AUTOMATIC THERAPY ADJUSTMENTS

[0001] The invention relates to medical devices, and more particularly, to medical devices used for chronic therapy provision.

[0002] A variety of types of medical devices are used for chronic, e.g., long-term, provision of therapy to patients. As examples, pulse generators are used for chronic provision of cardiac pacing and neurostimulation therapies, and pumps are used for chronic delivery of therapeutic agents, such as drugs. Typically, such devices provide therapy continuously or periodically according to parameters, e.g., a program, specified by a clinician.

[0003] In some cases, the patient is allowed to activate and/or modify the therapy. For example, the symptoms, e.g., the intensity of pain, of patients who receive spinal cord stimulation (SCS) therapy may vary over time based on the activity level or posture of the patient, the specific activity undertaken by the patient, or the like. For this reason, a patient who receives SCS therapy from an implantable medical device (IMD), e.g., an implantable pulse generator, is often given a patient programming device that communicates with his IMD via device telemetry, and allows the patient to activate and/or adjust the intensity of the delivered neurostimulation.

[0004] In general, the invention is directed to techniques for providing automatic adjustments to a therapy. A medical device, such as an implanted medical device (IMD) for delivering a therapy or a programming device, automatically adjusts delivery of the therapy in response to detecting a previously defined event. By automatically adjusting therapy in response to detecting a previously defined event, the medical device can automatically provide appropriate therapy to address changes in the symptoms of a patient, and/or changes in the efficacy or side effects of the therapy associated with the event. The medical device may deliver neurostimulation therapy, and an event may be an activity and/or posture undertaken by the patient, such as running or sitting in a chair, which will likely impact the type or level of symptoms and/or the paresthesia experienced by the patient.

[0005] In exemplary embodiments, the medical device enters a learning mode in response to a command received from a user, e.g., the patient. In such

embodiments, the medical device defines the event, collects the therapy information, and associates the therapy information with the defined event while operating in the learning mode. In some embodiments, the medical device defines the event based on an indication of the event received from the user. In other embodiments, the medical device defines the event based on the output of a sensor that indicates the activity, posture, or a physiological parameter of the patient during the learning mode. The sensor may be an accelerometer, which generates an output that reflects motion and/or posture of the patient. The medical device may collect therapy information by recording values of one or more therapy parameters, such as pulse amplitude, width and rate, and/or changes made to the parameters by the user during the learning mode.

[0006] When a patient undertakes certain activities and/or postures, the patient may experience an uncomfortable increase in the intensity of the neurostimulation delivered by a medical device. This phenomenon is referred to as a "jolt." Some of the events detected by the medical device may correspond to a jolt. In response to detecting these events, the medical device may suspend delivery of neurostimulation therapy for a period of time, which may advantageously allow the medical device avoid providing uncomfortable stimulation to the patient.

[0007] In one embodiment, the invention is directed to a method in which a command to enter a learning mode is received from a user. An event is defined, and therapy information is associated with the defined event, in response to the command. The defined event is subsequently detected, and therapy is provided to a patient via a medical device according to the therapy information in response to the detection.

[0008] In another embodiment, the invention is directed to a medical device that comprises a memory and a processor. The processor receives a command to enter a learning mode from a user, and defines an event and associates therapy information with the defined event within the memory in response to the command. The processor subsequently detects the event, and controls delivery of therapy to a patient according to the therapy information in response to the detection.

[0009] In another embodiment, the invention is directed to a computer-readable medium containing instructions. The instructions cause a programmable processor to receive a command from a user to enter a learning mode, and define and event and associate therapy information with the defined event in response to the command. The computer-readable medium further comprises instructions that cause a programmable processor to subsequently detect the defined event, and control delivery of therapy to a patient via a medical device according to the therapy information in response to the detection.

[0010] The invention may provide advantages. For example, by automatically adjusting therapy in response to a detected event, a medical device can provide therapy that better addresses changes in the symptoms of a patient and/or level of efficacy or side effects of the therapy associated with an activity undertaken by the patient. The medical device may automatically provide the appropriate therapy for frequently occurring events, e.g., activities that the patient frequently undertakes, allowing the patient to avoid having to manually adjust the therapy each time the event occurs. Manual adjustment of stimulation parameters can be tedious, requiring the patient to, for example, depress one or more keys of a keypad of a patient programmer multiple times during the event to maintain adequate symptom control. Instead, according to the invention, the patient may perform such adjustments a single time during a learning mode, and the medical device may automatically provide the adjustments during subsequent occurrences of the event.

[0011] FIG. 1 is a conceptual diagram illustrating an exemplary system that facilitates automatic discrete therapy adjustment according to the invention.

[0012] FIG. 2 is a block diagram illustrating an example medical device that provides therapy and automatically makes discrete adjustments to the therapy.

[0013] FIG. 3 is a block diagram illustrating an exemplary configuration of a memory of the medical device of FIG. 2.

[0014] FIG. 4 is a block diagram illustrating an example programming device that allows a user to communicate with the medical device of FIG. 2.

[0015] FIG. 5 is a flow diagram illustrating an exemplary operation of the medical device of FIG. 2 according to a learning mode.

[0016] FIG. 6 is a flow diagram illustrating another exemplary operation of the medical device of FIG. 2 according to a learning mode.

[0017] FIG. 7 is a flow diagram illustrating an exemplary operation of the medical device of FIG. 2 to provide discrete therapy adjustments according to the invention.

[0018] FIG. 8 is a timing diagram illustrating display of diagnostic information including learned events according to the invention.

[0019] FIG. 1 is a conceptual diagram illustrating an exemplary system 10 that facilitates automatic therapy adjustment according to the invention. In the illustrated example, system 10 includes an implantable medical device (IMD) 12, which is implanted within a patient 14, and delivers neurostimulation therapy to patient 14. In exemplary embodiments, IMD 12 takes the form of an implantable pulse generator, and delivers neurostimulation therapy to patient 14 in the form of electrical pulses.

[0020] IMD 12 delivers neurostimulation therapy to patient 14 via leads 16A and 16B (collectively "leads 16"). Leads 16 may, as shown in FIG. 1, be implanted proximate to the spinal cord 18 of patient 14, and IMD 12 may deliver spinal cord stimulation (SCS) therapy to patient 14 in order to, for example, reduce pain experienced by patient 14. However, the invention is not limited to the configuration of leads 16 shown in FIG. 1 or the delivery of SCS therapy. For example, one or more leads 16 may extend from IMD 12 to the brain (not shown) of patient 14, and IMD 12 may deliver deep brain stimulation (DBS) therapy to patient 14 to, for example, treat tremor or epilepsy. As further examples, one or more leads 16 may be implanted proximate to the pelvic nerves (not shown) or stomach (not shown), and IMD 12 may deliver neurostimulation therapy to treat incontinence or gastroparesis.

[0021] In exemplary embodiments, IMD 12 delivers therapy to patient 14 according to a program. A program includes one or more parameters that define an aspect of the therapy delivered by the medical device according to that program. For example, a program that controls delivery of neurostimulation by IMD 12 may define a voltage or current pulse amplitude, a pulse width, a pulse rate, for stimulation pulses delivered by IMD 12 according to that program. Further, each of leads 16 includes electrodes (not shown in FIG. 1), and the parameters for a

program that controls delivery of neurostimulation therapy by IMD 12 may include information identifying which electrodes have been selected for delivery of pulses according to the program, and the polarities of the selected electrodes.

[0022] In the illustrated example, system 10 also includes a programming device 20, which is a medical device, and may, as shown in FIG. 1, be a handheld computing device. Programming device 20 allows a user to interact with IMD 12. Programming device 20 may, for example, communicate via wireless communication with IMD 12 using RF telemetry techniques known in the art.

[0023] Programming device 20 may, as shown in FIG. 1, include a display 22 and a keypad 24 to allow the user to interact with programming device 20. In some embodiments, display 22 may be a touch screen display, and the user may interact with programming device 20 via display 22. The user may also interact with programming device 20 using peripheral pointing devices, such as a stylus or mouse. Keypad 24 may take the form of an alphanumeric keypad or a reduced set of keys associated with particular functions.

[0024] In exemplary embodiments, programming device 20 is a patient programmer used by patient 14 to control the delivery of neurostimulation therapy by IMD 12. Patient 14 may use programming device 20 to activate or deactivate neurostimulation therapy. Patient 14 may also use programming device 20 to adjust one or more program parameters, e.g., adjust the amplitude, width, or rate of delivered stimulation pulse. Where more than one program is available to IMD 12 for delivery of neurostimulation to patient 14, patient 14 may use programming device 20 to select from among the available programs. The programs available for selection by patient 14 may be stored in either of IMD 12 and programming device 20.

[0025] As will be described in greater detail below, one or both of IMD 12 and programming device 20 provide automatic adjustment of the therapy delivered by IMD 12 according to the invention. Specifically, one of IMD 12 and programming device 20 detects a previously defined event, and the delivery of therapy by IMD 12 is automatically adjusted according to therapy information stored in association with defined event. In exemplary embodiments, the one of IMD 12 and programming device 20 may make automatic adjustments to the therapy over a

period of time in response to detection of the previously defined event, e.g., provide a series of therapy adjustments defined by the therapy information associated with the event. By automatically adjusting therapy in response to a detected event, system 10 can provide therapy that better addresses changes in the symptoms of patient 14 associated with the event.

[0026] For ease of description, the provision of automatic therapy adjustment will be described hereinafter primarily with reference to embodiments in which IMD 12 provides automatic therapy adjustments. However, it is understood that both of IMD 12 and programming device 20 are medical devices capable of providing automatic therapy adjustments according to the invention.

[0027] In exemplary embodiments, IMD 12 provides a learning mode. IMD 12 may enter the learning mode in response to a command received from a user. For example, patient 14 may direct IMD 12 to enter the learning mode via keypad 24 of patient programmer 20.

[0028] When operating in the learning mode, IMD 12 defines events and associates therapy information with the events. In some embodiments, IMD 12 defines the event based on the indication of the event to IMD 12 by a user. In such embodiments, IMD 12 later detects the event by receiving the indication from the user, and automatically adjusts therapy according to information stored in association with that indication, e.g., with the event.

[0029] For example, patient 14 may indicate the occurrence of an event to IMD 12 via keypad 24 of patient programmer 20. In some embodiments, a particular key of keypad 24 is associated with the event. The event may correspond to an activity undertaken by patient 14, such as running, golfing, taking medication, sleeping, or a particular activity related to an occupation of patient 14. A first time patient 14 undertakes the activity, the activity, e.g., event, may be associated with a key of keypad 24. Subsequent times patient 14 undertakes the activity, patient 14 may press the key to cause IMD 12 to provide therapy adjustment according to therapy information associated with depression of the key.

[0030] In other embodiments, IMD 12 defines the event based on the output of a sensor (not shown in FIG. 1). IMD 12 may monitor the sensor output in response to the command to enter the learning mode received from the user, e.g., patient 14.

After the event is defined, IMD 12 may monitor the output of the sensor, and, if the event is subsequently detected, provide automatic therapy adjustment according to information stored in association with the event. For example, IMD 12 may record the sensor output for a period during the learning mode to define the event, and, when no longer operating in the learning mode, apply digital signal and/or pattern recognition analysis techniques to the sensor output to automatically identify subsequent occurrences of the event based on comparison to the recorded exemplar.

[0031] The output of the sensor may reflect motion, posture, and/or one or more physiological parameters of patient 14. Consequently, events defined by IMD 12 based on the sensor output may correspond to an activity undertaken by patient 14. For example, patient 14 may direct IMD 12 to enter the learning mode via patient programmer 20 when patient 14 is about to undertake an activity, such as running. IMD 12 may record the output of the sensor in response to the command, and, when no longer in the learning mode, use the recorded exemplar to detect when patient 14 is running so as to automatically provide an appropriate therapy adjustment according to therapy information stored in association with the exemplar.

[0032] IMD 12 may associate therapy information with the defined event while operating in the learning mode, and provide therapy, e.g., automatically adjusts the therapy, according to the therapy information in response to subsequent detection of the defined event. The therapy information may be the values of one or more parameters, e.g., pulse amplitude, pulse width, or pulse rate, recorded by IMD 12 upon entering, or at some point after entering, the learning mode. The therapy information may be a change to a parameter made by a user while IMD 12 is operating in the learning mode. In exemplary embodiments, IMD 12 records a series of changes made to parameters by the user over a period of time while IMD 12 is operating in the learning mode.

[0033] For example, patient 14 may direct IMD 12 to enter the learning mode so that IMD 12 will learn the appropriate adjustment or adjustments to make to the stimulation parameters while patient 14 is running. Patient 14 may indicate the occurrence of the event to IMD 12, e.g., may associate a key of keypad 24 with the

activity of running, or may simply begin running and allow IMD 12 to record an exemplar of the sensor output while patient 14 is running. In any case, while patient 14 is running during the learning mode, patient 14 uses programming device 20, e.g., keypad 24, to change one or more stimulation parameters in an attempt to maintain adequate symptom control during the activity. IMD 12 may record the value of the parameters when patient 14 indicates satisfaction, or the one or more changes made by patient 14 over a period of time while running. IMD 12 stores the values or a recording of the changes over the time period in association with the event, and, when no longer operating in the learning mode, delivers therapy according to the therapy information upon subsequently detecting that patient 14 is running.

[0034] By associating therapy information with defined events, IMD 12 may automatically provide appropriate therapy to patient 14 for frequently occurring events, e.g., activities that patient 14 frequently undertakes. By providing therapy adjustments automatically, IMD 12 may allow patient 14 to avoid having to manually adjust the therapy each time the event occurs. Such manual adjustment of stimulation parameters can be tedious, requiring patient 14 to, for example, depress one or more keys of keypad 24 multiple times during the event to maintain adequate symptom control. Instead, according to the invention, patient 14 may perform such adjustments a single time during the learning mode, and IMD 12 may automatically provide the adjustments during subsequent occurrences of the event.

[0035] FIG. 2 is a block diagram illustrating IMD 12 in greater detail. IMD 12 may deliver neurostimulation therapy via electrodes 30A-D of lead 16A and electrodes 30E-H of lead 16B (collectively "electrodes 30"). Electrodes 30 may be ring electrodes. The configuration, type and number of electrodes 30 illustrated in FIG. 2 are merely exemplary.

[0036] Electrodes 30 are electrically coupled to a therapy delivery circuit 32 via leads 16. Therapy delivery circuit 32 may, for example, include an output pulse generator coupled to a power source such as a battery. Therapy delivery circuit 32 may deliver electrical pulses to patient 14 via at least some of electrodes 30 under the control of a processor 34.

[0037] Processor 34 may control therapy delivery circuit 32 to deliver neurostimulation therapy according to a selected program. Specifically, processor 34 may control circuit 32 to deliver electrical pulses with the amplitudes and widths, and at the rates specified by the program. Processor 34 may also control therapy delivery circuit 32 to deliver the pulses via a selected subset of electrodes 30 with selected polarities, as specified by the program.

[0038] Processor 34 may also provide a learning mode of IMD 12 as described above. Specifically, processor 34 may receive commands from a user to enter the learning mode, may define an event during the learning mode, and may associate therapy information with the defined event within memory 36, as described above. When processor 34 is no longer operating in the learning mode, processor 34 and/or monitor 42 may detect previously defined events, and control therapy delivery circuit 32 to deliver therapy via at least some of electrodes 30 as indicated by the associated therapy information. Specifically, processor 34 may control therapy delivery circuit to deliver stimulation pulses with the amplitude, width, and rate indicated by the therapy information, and, in some embodiments, may control therapy delivery circuit to adjust the amplitude, width, and/or rate over time as indicated by the therapy information.

[0039] IMD 12 also includes a telemetry circuit 38 that allows processor 34 to communicate with programming device 20. Processor 34 may receive program selections, commands to enter a learning mode, indications of events, and adjustments to therapy made by a user, e.g., patient 14, using programming device 20 via telemetry circuit 38. In some embodiments, as will be described in greater detail below, processor 34 communicates with a clinician programmer to provide diagnostic information stored in memory 36 to a clinician via telemetry circuit 38. Telemetry circuit 38 may correspond to any telemetry circuit known in the implantable medical device arts.

[0040] In exemplary embodiments, as described above, IMD 12 includes a sensor 40, and processor 34 defines events based on the output of sensor 40. Sensor 40 is a sensor that generates an output based on motion, posture, and/or one or more physiological parameters of patient 14. In exemplary embodiments, sensor 40 is

an accelerometer, such as a piezoresistive and/or micro-electro-mechanical accelerometer.

[0041] In some embodiments, IMD 12 includes an activity/posture monitor 42 that processes the analog output of sensor 40 to provide digital activity and/or posture information to processor 34. For example, where sensor 40 comprises a piezoresistive accelerometer, monitor 42 may process the raw signal provided by sensor 40 to provide activity counts to processor 34. In some embodiments, IMD 12 includes multiple sensors oriented along various axes, or sensor 40 comprises a single multi-axis, e.g., three-axis, accelerometer. In such embodiments, monitor 42 may process the signals provided by the one or more sensors 40 to provide velocity of motion information for each direction to processor 34.

[0042] In exemplary embodiments, the one or more sensors 40 are housed within a housing (not shown) of IMD 12. However, the invention is not so limited. In some embodiments, one or more sensors 40 are coupled to monitor 42 housed within IMD 12 via additional leads 16 (not shown). Such sensors may be located anywhere within patient 14. In some embodiments, IMD 12 may include multiple accelerometer sensors 40 located at various positions within patient 14 or on the external surface of patient 14, and processor 34 may receive more detailed information about the posture of and activity undertaken by patient 14. For example, accelerometer sensors 40 may be located within the torso and at a position within a limb, e.g. a leg, of patient 14.

[0043] Sensors 40 may be coupled to a single monitor 42, or IMD 12 may include multiple monitors 42 coupled to one or more sensors 40. Further, the invention is not limited to embodiments of IMD 12 that include a monitor 42. Rather, sensors 40 may be coupled directly to processor 34, which may include an analog-to-digital converter, and perform the functions attributed to monitor 42. In some embodiments, sensors located external to patient 14 may communicate wirelessly with processor 34, either directly or via programming device 20. In some embodiments, one or more sensors 40 may be included as part of or coupled to programming device 20.

[0044] Moreover, the invention is not limited to embodiments where sensors 40 are accelerometers. In some embodiments, one or more sensors 40 may take the

form of, for example, a thermistor, a pressure transducer, or electrodes to detect thoracic impedance or an electrogram. Such sensors 40 may be appropriately positioned within or on an external surface of patient 14 to measure a physiological parameter of patient 14, such as a skin temperature, an arterial or intracardiac pressure, a respiration rate, a heart rate, or a Q-T interval of patient 14. In such embodiments, one or more monitor circuits 42 may provide appropriate circuitry to process the signals generated by such sensors, and to provide values of the physiological parameter to processor 34.

[0045] Processor 34 may include a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), discrete logic circuitry, or the like. Memory 36 may include program instructions that, when executed by processor 34, cause IMD 12 to perform the functions ascribed to IMD 12 herein. Memory 36 may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, and the like.

[0046] FIG. 3 is a block diagram illustrating an exemplary configuration of memory 36 of IMD 12. In some embodiments, memory 36 stores the one or more programs 50 used by processor 34 (FIG. 2) to control delivery of stimulation by therapy delivery circuit 32 (FIG. 2). Processor 34 may receive the programs from a clinician via a clinician programming device and telemetry circuit 38 (FIG. 2), and store the programs in memory 36. In other embodiments, programs 50 are stored within a memory of programming device 20, and provided to processor 34 via telemetry circuit 38 as needed.

[0047] Memory 36 stores events 52 defined by processor 34 during operation in the learning mode, and learned therapies 54, i.e., the therapy information collected during operation in the learning mode. As described above, an event 52 may be information describing an event indication received from a user, e.g., patient 14 (FIG. 1), during the learning mode. For example, an event 52 may indicate a signal received via telemetry circuit 38 when patient presses a key of keypad 24 (FIG. 1) that patient 14 has associated with an activity undertaken by patient 14.

[0048] In some embodiments, as described above, processor 34 defines events 52 based on the output of one or more sensors 40. Processor 34 may store one or more sample of the output of sensor 40 and/or monitor 42 collected while operating in the learning mode as an event, or one or more results of an analysis such samples. For example, processor 34 may store information related to the detection of features within the one or more samples, such as peaks, zero-crossings, or the like, or the results of a Fourier or wavelet analysis of the one or more samples as a defined event 52.

[0049] As described above, learned therapies 54 comprises information describing values of stimulation parameters and/or information describing one or more changes to parameters made by a user while processor 34 is operating in the learning mode. In exemplary embodiments, a learned therapy 54 comprises information describing initial parameter values and changes to be made to some or all of the parameter values over a period of time. In such embodiments, the learned therapy may include time values associated with parameter values, so that processor 34 may direct changes to parameter values at appropriate times. Memory 36 maintains associations between events 52 and corresponding learned therapies 54.

[0050] Processor 34 may also collect diagnostic information 56 and store diagnostic information 56 within memory 36 for future retrieval by a clinician. Diagnostic information 56 may, for example, include selected recordings of the output of sensor 40 and/or of therapy changes made by patient 14. In exemplary embodiments, diagnostic information 56 includes information identifying the time at which defined events occurred, either during operation in a learning mode or as subsequently detected by processor 34. Diagnostic information 56 may include other information or events indicated by patient 14 outside of learning mode using programming device 20, such as changes in symptoms, taking medication, or other activities undertaken by patient 14 for which patient 14 does not wish IMD 12 to learn a therapy. A clinician programming device (not shown in FIGS.) may present diagnostic information 56 to a clinician in a variety of forms, such as timing diagrams, or a graph resulting from statistical analysis of diagnostic information 56, e.g., a bar graph.

[0051] FIG. 4 is a block diagram further illustrating programming device 20. As indicated above, in exemplary embodiments programming device 20 takes the form of a patient programming device used by patient 14 to control delivery of therapy by IMD 12. Patient 14 may interact with a processor 60 via a user interface 62 in order to control delivery of neurostimulation therapy, direct IMD 12 to enter a learning mode, indicate events and make therapy changes, as described herein. User interface 62 may include display 22 and keypad 24, and may also include a touch screen or peripheral pointing devices as described above.

Processor 60 may also provide a graphical user interface (GUI) to facilitate interaction with patient 14. Processor 60 may include a microprocessor, a controller, a DSP, an ASIC, an FPGA, discrete logic circuitry, or the like.

[0052] Programming device 20 also includes a telemetry circuit 64 that allows processor 60 to communicate with IMD 12. In exemplary embodiments, processor 60 communicates commands, indications, and therapy changes made by patient 14 via user interface 62 to IMD 12 via telemetry circuit 64. Telemetry circuit 64 may correspond to any telemetry circuit known in the implantable medical device arts.

[0053] Programming device also includes a memory 66. In some embodiments, memory 66, rather than memory 36 of IMD 12, may store programs 50 that are available to be selected by patient 14 for delivery of neurostimulation therapy. Memory 66 may also include program instructions that, when executed by processor 60, cause programming device 20 to perform the functions ascribed to programming device 20 herein. Memory 66 may include any volatile, non-volatile, fixed, removable, magnetic, optical, or electrical media, such as a RAM, ROM, CD-ROM, hard disk, removable magnetic disk, memory cards or sticks, NVRAM, EEPROM, flash memory, and the like.

[0054] FIG. 5 is a flow diagram illustrating an exemplary operation of IMD 12 according to a learning mode. Specifically, FIG. 5 illustrates an exemplary mode of IMD 12 to learn a therapy for an event that is indicated by patient 14. Processor 34 enters the learning mode in response to receiving a command from patient 14 (70). Patient 14 may direct processor 34 to enter the learning mode by pressing a key of keypad 24 of programming device 20.

[0055] When operating in the learning mode, processor 34 defines an event 52 by receiving an indication from patient 14 (72). Patient 14 may indicate the event by, for example, pressing a key of keypad 24 that patient will thereafter use to identify the event to processor 34. The event 52 may be an activity and/or posture to be undertaken by patient 14, and the key may be used by patient 14 in the future to indicate to processor 34 that patient 14 is about to undertake the activity. Processor 34 may store information identifying the signal received by via telemetry circuit 38 when patient presses the key as the event 52 within memory 36.

[0056] Processor 34 then records therapy information, e.g., a learned therapy 54, while operating in the learning mode (74). As described above, the learned therapy 54 may be stimulation parameter values and/or one or more changes made to stimulation parameters by patient 14 over a period of time during operation within the learning mode. Processor 34 may store therapy information as a learned therapy at any time after receiving the command to enter the learning mode, e.g., before or after receiving an indication of the event from patient 14. Processor 34 stores the learned therapy 54 within memory 36, and associates the learned therapy 54 with the defined event 52 within memory 36 (76).

[0057] In exemplary embodiments, patient 14 adjusts stimulation parameters over a period of time after directing IMD 12 to enter the learning mode, e.g., during the event. For example, patient 14 may direct IMD 12 to enter the learning mode, so that IMD 12 learns appropriate adjustments to therapy to provide while patient 14 is running, and may adjust stimulation parameters while running to maintain effective and comfortable neurostimulation therapy. IMD 12 may store the stimulation parameters and/or changes to the stimulation parameters and associate times with the parameters or changes, so that stimulation according to the parameters and changes to the stimulation may be provided at appropriate times during a subsequent occurrence of patient 14 running.

[0058] In other embodiments, rather than IMD 12 recording therapy information over time, patient 14 may use programming device 20 to enter a learned therapy 54 that includes time as a parameter. For example, patient 14 may create a learned therapy 54 for the "running" event that includes increases to pulse amplitude and

width at particular time after the event is detected by IMD 12, and/or after N minutes that the event continues to be detected by IMD 12.

[0059] FIG. 6 is a flow diagram illustrating another exemplary operation IMD 12 according to a learning mode. Specifically, FIG. 6 illustrates an exemplary mode of IMD 12 to learn a therapy for an event that is defined by IMD 12 based on the output of a sensor 40. Processor 34 enters the learning mode in response to receiving a command from patient 14 (80).

[0060] While operating in the learning mode, processor 34 records at least one of the output of sensor 40 or the information provided by monitor circuit 42 based on the sensor output (82). Processor 34 may record the sensor output or information over any length of time, may record multiple samples, and may make the recording or recordings at any time after entering the learning mode. Processor 34 may store the recording(s), or the result of an analysis, e.g. feature, Fourier, or wavelet, or the recording(s) in memory 36 as an event 52. Processor 34 records therapy information as a learned therapy 54 during operation in the learning mode (84), and associates the learned therapy 54 with the defined event 52 (86), as described above with reference to FIG. 5.

[0061] FIG. 7 is a flow diagram illustrating an exemplary operation of IMD 12 to provide automatic therapy adjustments according to the invention. Processor 34 monitors signals received from programming device 20 via telemetry circuit 38, and output of sensor 40 and/or monitor circuit 42, to detect previously defined events 52 (90). To monitor the sensor output, processor 34 compares the current sensor output to the event. 52. For example, processor 34 can compare the current sensor output to the sample sensor output recorded during operation in the learning mode, or the result of a signal analysis of the current sensor output to the result of a signal analysis of the sample sensor output recorded during operation in the learning mode. Processor 34 may use any of a variety of known pattern matching techniques or algorithms, such as fuzzy logic or neural network techniques or algorithms, to subsequently detect the previously defined events 52.

[0062] If processor 34 detects a previously defined event 52 (92), processor 34 controls therapy delivery circuit 32 to deliver therapy according to the learned therapy 54 associated with the detected event 52 in memory 36 (94). Processor 34

may control circuit 32 to deliver therapy according to parameter values of the learned therapy 54. Processor 34 may also control circuit 32 to change the parameter values over time according to the learned therapy 54.

[0063] If processor 34 detects that patient 14 has made changes to stimulation parameters during provision of therapy according to the learned therapy 54 (96), processor 34 may query patient 14 via programming device 20 as to whether the changes should be saved as a modification to the learned therapy 54 (98). If patient 14 wishes to save the changes, processor 34 modifies the learned therapy 54 according to the changes (100).

[0064] As described above, an event 52 may be an activity or posture undertaken by patient 14. For example, an event 52 may be patient 14 running, and the learned therapy 54 may include changes to stimulation parameters occurring at associated times during the "running" event such that effective and comfortable therapy is maintained. Other activities and postures that may effect the symptoms experienced by patient 14, or the effectiveness and side effects of the stimulation may include golfing, gardening, driving a car, sitting in a chair, twisting, or bending over. In some cases the duration of a particular activity or posture may affect the symptoms experienced by patient 14, or the effectiveness and side effects of the stimulation. In such cases an event 52 may be defined as occurring after patient 14 maintains an activity or posture for a defined duration.

[0065] In some cases, an activity or posture undertaken by patient 14 results in an uncomfortable increase in the intensity of the stimulation delivered by IMD 12. This phenomenon is referred to as a "jolt." Activities and postures that may lead to "jolts" include sitting in a seat, twisting, bending over, rapid posture changes, or other like postures or transitions between postures. Patient 14 may use the learning mode provided by IMD 12 as described herein to cause IMD 12 to define events 52 associated with the activities or postures that lead to "jolts," and associate such "jolt" events with therapy information 54 that causes IMD 12 to suspend or reduce the intensity of stimulation upon subsequent detection of the "jolt" events. Consequently, embodiments of IMD 12 may advantageously provide efficacious therapy during certain defined events 52, and avoid providing uncomfortable therapy during other defined events 52.

[0066] FIG. 8 is a timing diagram illustrating display of diagnostic information 56 including learned events 52 according to the invention. As described above, in some embodiments processor 34 collects diagnostic information for review by a clinician that may include defined events, events indicated by patient 14 outside of the learning mode, the output of sensor 40 and/or monitor circuit 42, stimulation parameter values and/or changes made thereto over time, or the like. Diagnostic information 56 may be retrieved from IMD 12 by a clinician programmer and presented to a clinician in a variety of forms, such as the illustrated timing diagram, or various graphs, such as bar graphs, illustrating the result of a statistical analysis of diagnostic information 56. A clinician may use diagnostic data 56 to, for example, objectively assess patient activity, therapy effectiveness, patient compliance, or the like.

[0067] In the illustrated timing diagram, a curve 110 representing the activity level of patient 14, e.g., the output of one or both of sensor 40 and monitor 42, over time is displayed. Markers 112A-E are used to indicate the occurrence of events, which may be defined events 52. A second curve 114 illustrates the symptom, e.g., pain, intensity indicated by patient 14 over time. Curve 114 may be estimated based on intensity values 116A-F periodically entered by patient 14 using programming device 20.

[0068] Various embodiments of the invention have been described. However, one skilled in the art will appreciate that various modifications may be made to the described embodiments. For example, the invention is not limited to medical devices that deliver neurostimulation therapy or to implantable medical devices. Rather, systems that facilitate automatic therapy adjustment according to the invention may include one or more implantable or external medical devices, of any type, that deliver therapy to a patient. For example, in some embodiments, an implantable or external pump that delivers a therapeutic agent to a patient can provide automatic therapy adjustment according to the invention.

[0069] In some embodiments, a medical device that does not itself deliver therapy, such as a programming device, provides automatic therapy adjustment according to the invention. In such embodiments, the programming device may receive a command to enter a learning mode, an indication of an event, and therapy changes

from the patient via a keypad, for example. The programming device may include a memory to store defined events and associated therapy information. When the user, e.g., the patient, again indicates occurrence of the event to the programming device via the keypad, the programming device controls a therapy delivery device to deliver therapy according to therapy information associated with the defined event.

[0070] The invention is not limited to embodiments wherein a programming device is a patient programmer. For example, in some embodiments, a programming device may be a clinician programmer used by a clinician to, for example, create the programs that control the delivery of therapy by a therapy delivery device. The clinician may use the clinician programmer, during a programming session for example, to cause the clinician programmer or the therapy delivery device to learn therapies for defined events as described herein

[0071] In other embodiments, a system that facilitates automatic therapy adjustment does not include a programming device at all. Where a system includes an external medical device that provides therapy to a patient, for example, a user may interact with a user interface provided by the medical device and a programming device may therefore be unnecessary. A user may also interact with an implanted medical device using a magnetic activator, or by tapping over the implanted medical device, which may be detected via an accelerometer, as is known in the art.

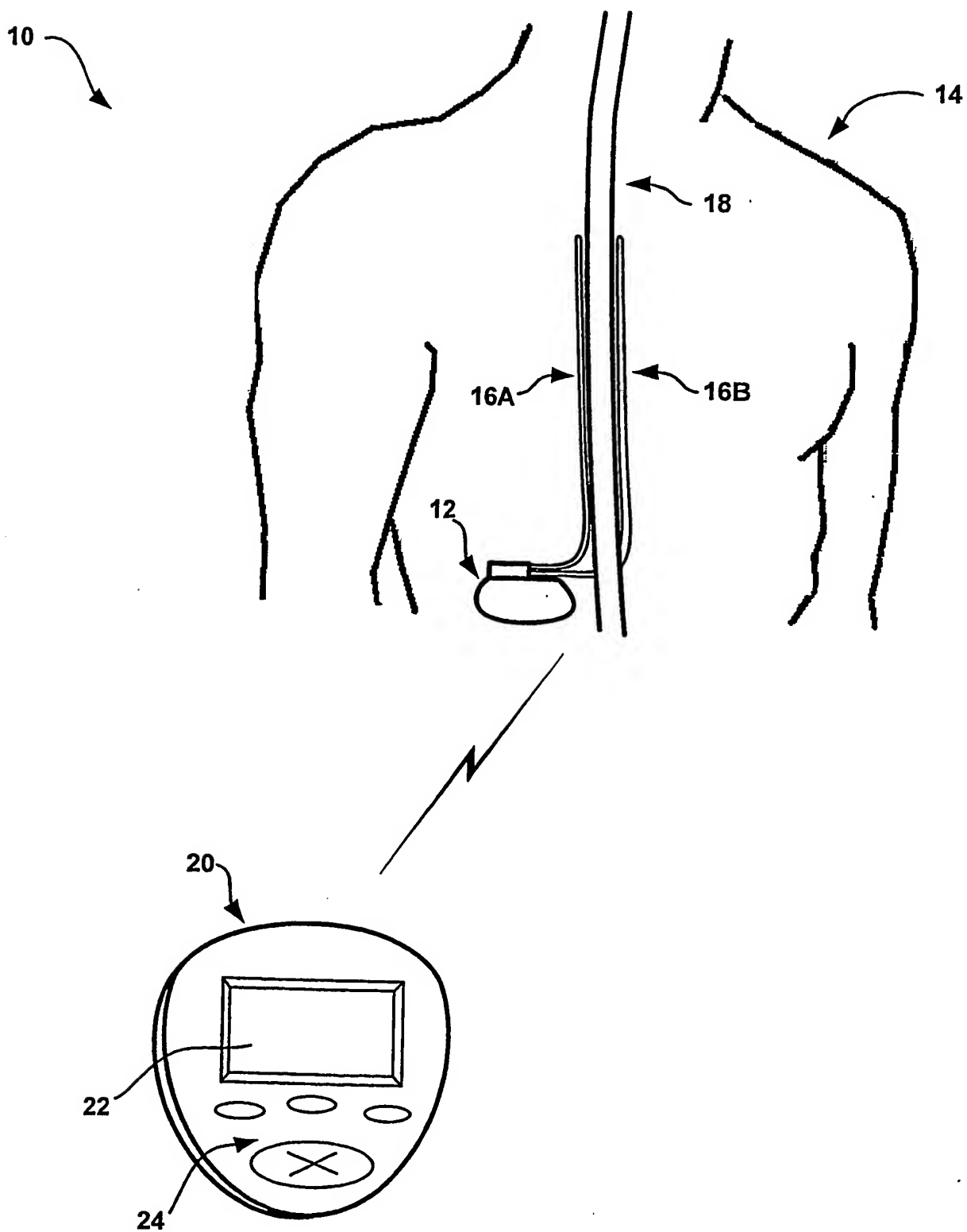
CLAIMS:

1. A medical device comprising:
a memory; and
a processor to receive a command to enter a learning mode from a user, define an event and associate therapy information with the defined event within the memory in response to the command, subsequently detect the defined event, and control delivery of therapy to a patient according to the therapy information in response to the detection.
2. The medical device of claim 1, wherein the processor defines the event and subsequently detects the defined event by receiving indications of the event from the user.
3. The medical device of claim 2, wherein the event comprises at least one of an activity and a posture undertaken by the patient, and the processor receives indications of the at least one of an activity and posture from the user.
4. The medical device of claim 1, further comprising a sensor that generates an output as a function of a physiological parameter of the patient, wherein the processor monitors the output of the sensor in response to receiving the command from the user, defines the event based on the sensor output, and subsequently detects the defined event by monitoring the output of the sensor and comparing the sensor output to the defined event.
5. The medical device of claim 4, wherein the sensor output reflects at least one of motion and posture of the patient.
6. The medical device of claim 4, wherein the sensor comprises an accelerometer.

7. The medical device of claim 6, wherein the accelerometer comprises a multi-axis accelerometer.
8. The medical device of claim 4, wherein the processor defines the event by storing a recording of the sensor output over a period of time after receipt of the command within the memory.
9. The medical device of claim 1, wherein the therapy information comprises a value of a parameter that controls delivery of therapy to the patient, and the processor associates the value and the defined event within the memory in response to the command.
10. The medical device of claim 9, wherein the therapy information reflects a change to the parameter made by the user subsequent to providing the command, and the processor records the change and associates the recorded change with the defined event within the memory in response to the command.
11. The medical device of claim 10, wherein the therapy information reflects changes to the parameter made by the user over a period of time subsequent to providing the command,
the processor records the changes over the period of time and associates the recorded changes with the defined event within the memory in response to the command, and
the processor provides therapy to the patient according to the therapy information by changing the therapy parameter at a time subsequent to detection of the defined event according to the recorded changes to the therapy parameter associated with the defined event.
12. The medical device of claim 9, wherein the processor receives the value of the parameter and a time from the user, and changes delivery of therapy at a time subsequent to detection of the defined event according to the value and time received from the user.

13. The medical device of claim 1, wherein the processor stores the defined event within the memory as diagnostic data for presentation to a clinician.
14. The medical device of claim 13, wherein the processor presents the defined event to the clinician as a marker within a timing diagram.
15. The medical device of claim 1, wherein the processor suspends delivery of therapy in response to the detection of the previously defined event.
16. The medical device of claim 1, wherein the medical device comprises an implantable neurostimulator.
17. The medical device of claim 1, wherein the medical device comprises a programming device that communicates with an implantable medical device.
18. The medical device of claim 1, wherein the user is one of a clinician and the patient.

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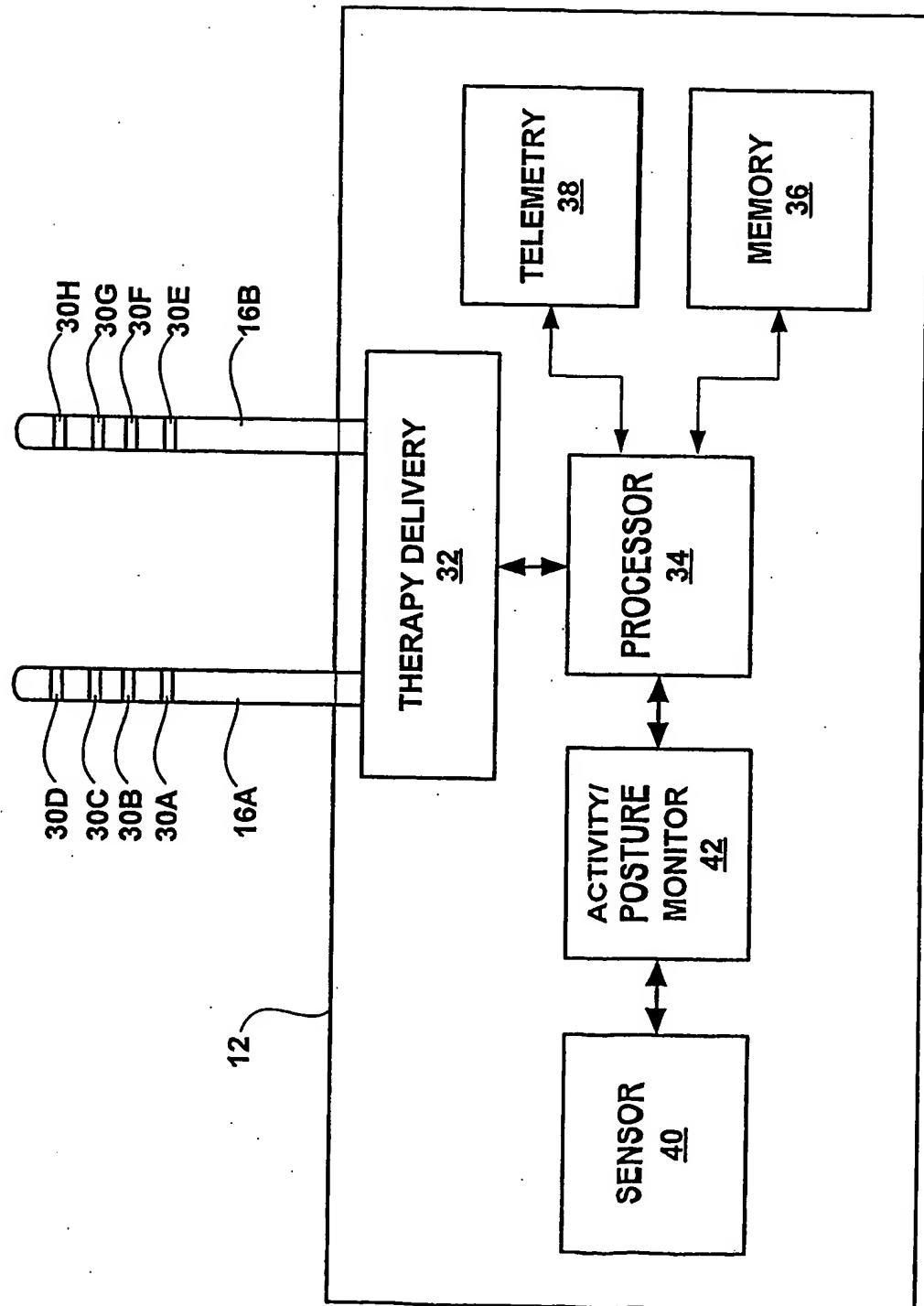


FIG. 2

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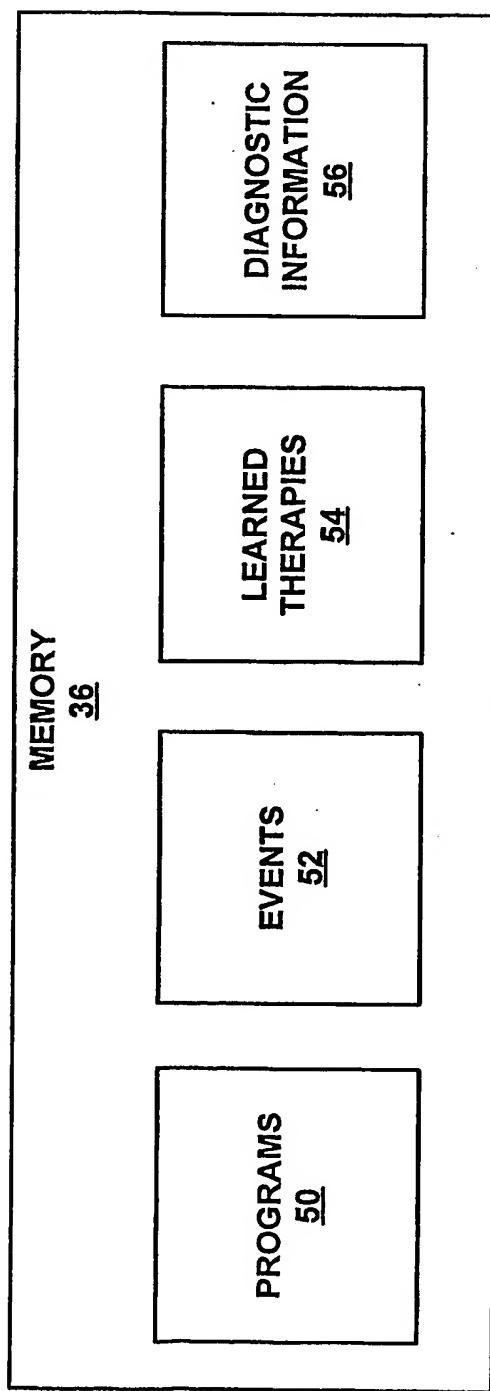
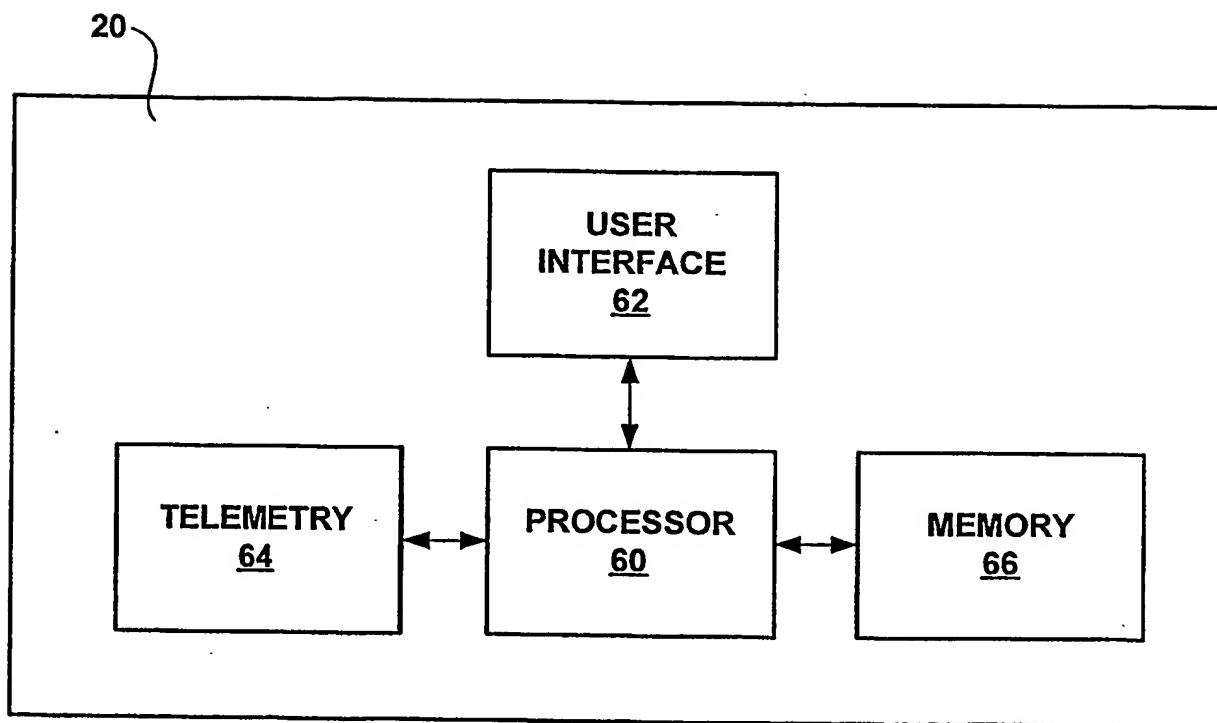


FIG. 3

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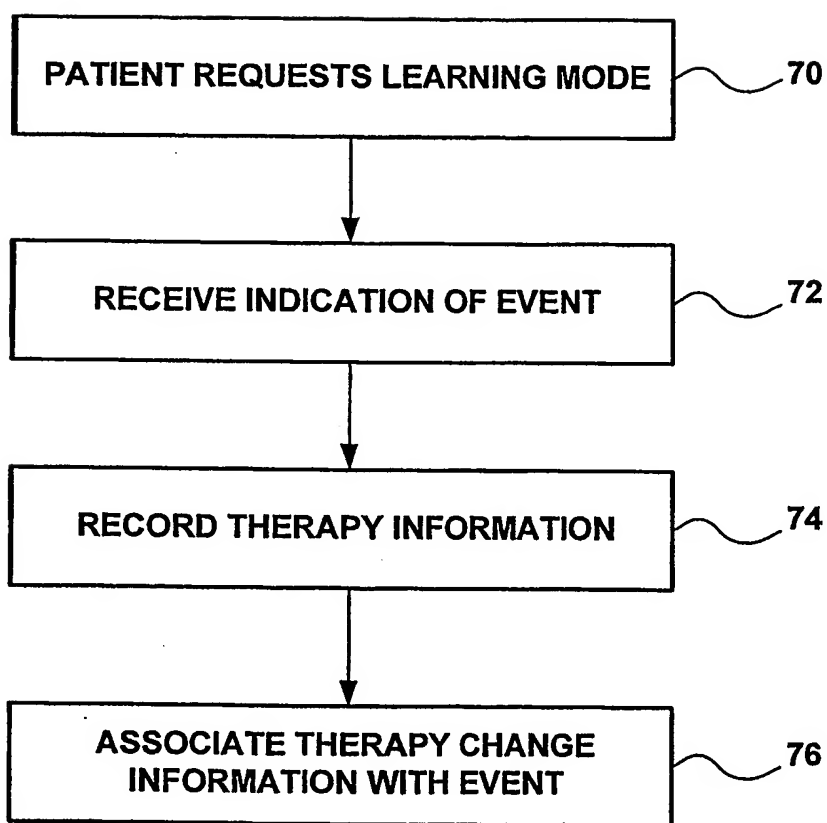


FIG. 5

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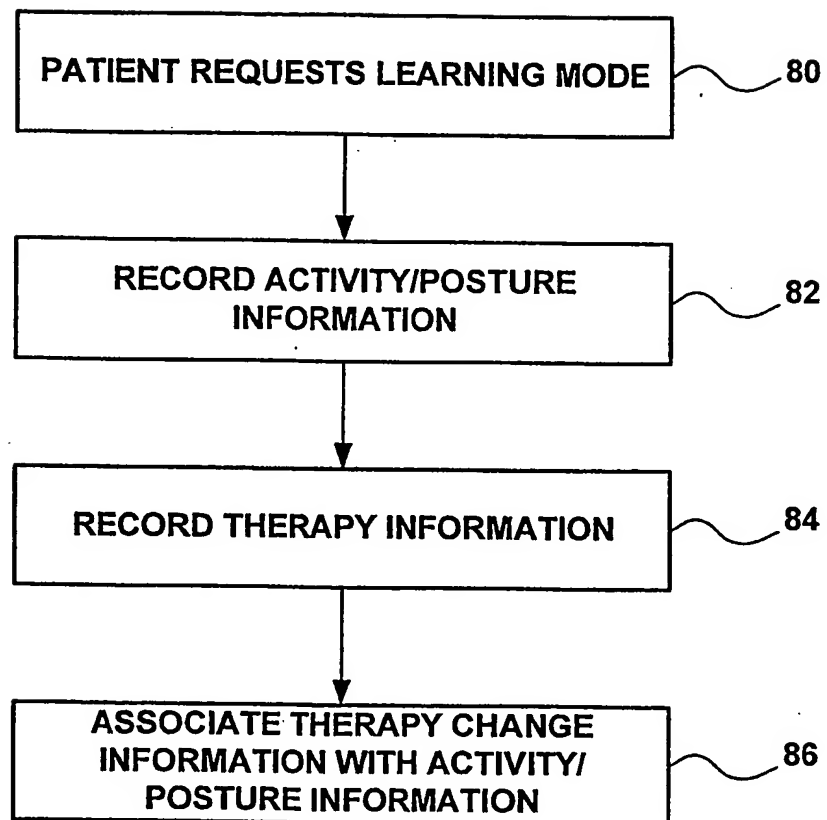


FIG. 6

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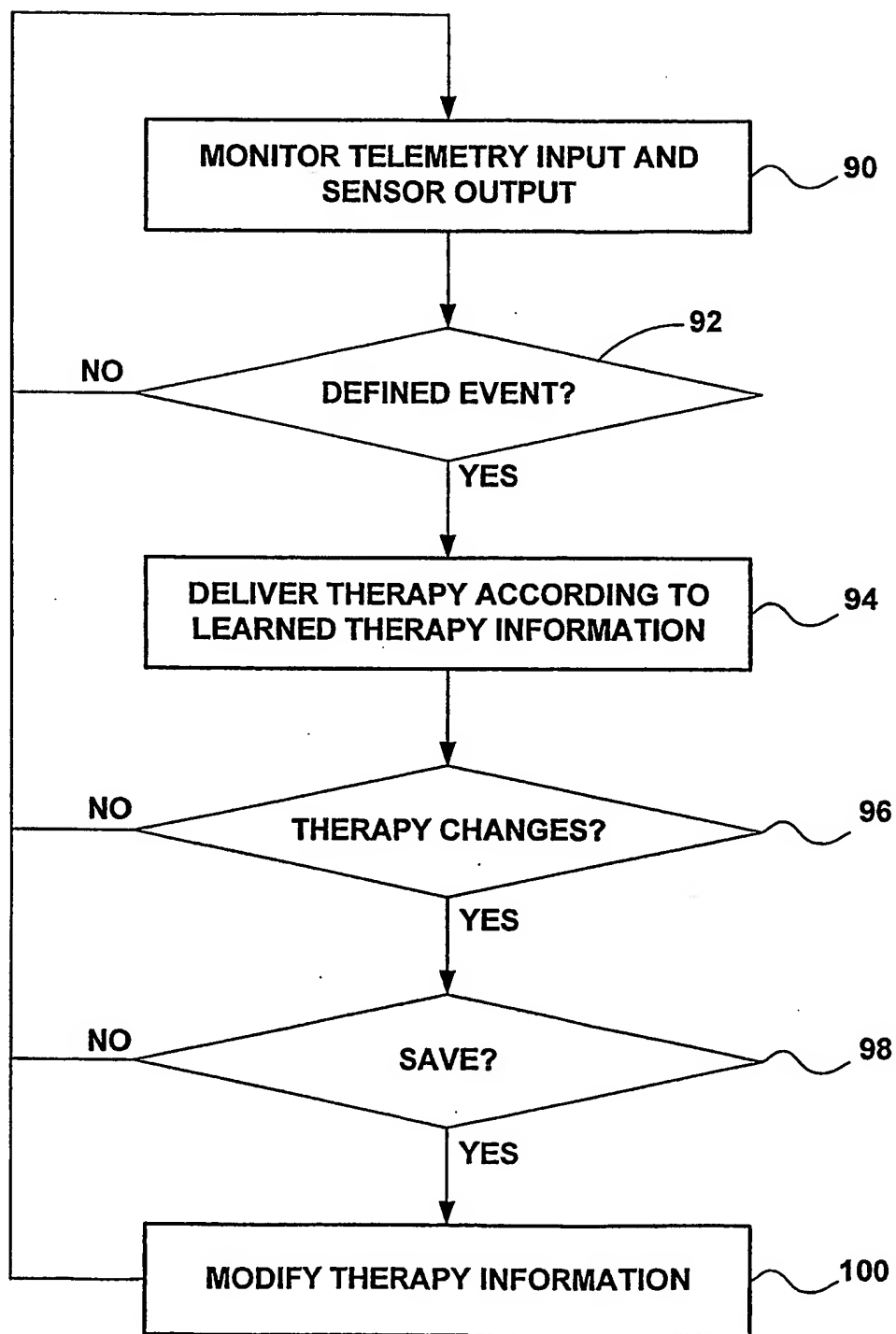


FIG. 7

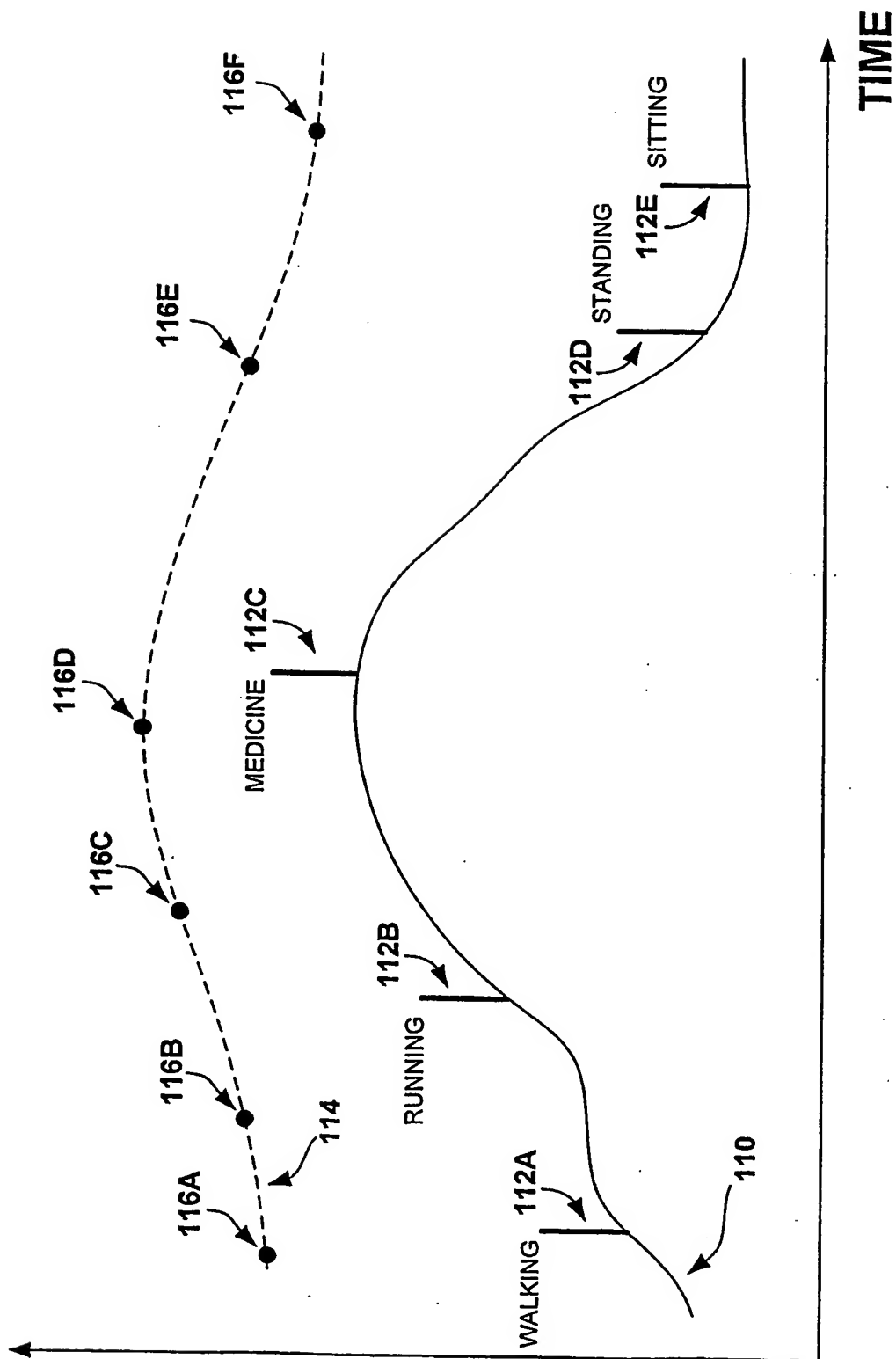


FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/002113

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/08 A61B5/103 A61B5/11 A61N1/37

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 440 090 B1 (SCHALLHORN RICK) 27 August 2002 (2002-08-27) column 1, line 22 -column 2, line 46; claim 1	1-6,8, 10-15,18
P,Y	US 6 635 048 B1 (ALI IRFAN Z ET AL) 21 October 2003 (2003-10-21) column 2, line 56 -column 3, line 18	1
Y	WO 96/29007 A (WALKER DAVID JOHN) 26 September 1996 (1996-09-26) abstract; claim 1	1
A	US 5 487 755 A (SNELL JEFFERY D ET AL) 30 January 1996 (1996-01-30) column 6, line 1 -column 7, line 15	1-18
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Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 720 770 A (CROSBY PETER ET AL) 24 February 1998 (1998-02-24) the whole document	1-18

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Information on patent family members

International Application No

PCT/US2004/002113

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6440090	B1	27-08-2002	US 6120467 A EP 1075305 A1 WO 9956820 A1	19-09-2000 14-02-2001 11-11-1999
US 6635048	B1	21-10-2003	US 6282450 B1 DE 10120279 A1 IE 20010274 A1 US 2004030323 A1 EP 1048323 A2	28-08-2001 20-12-2001 03-04-2002 12-02-2004 02-11-2000
WO 9629007	A	26-09-1996	AU 5010896 A WO 9629007 A1 GB 2313672 A , B	08-10-1996 26-09-1996 03-12-1997
US 5487755	A	30-01-1996	US 5431691 A US 5487754 A	11-07-1995 30-01-1996
US 5720770	A	24-02-1998	NONE	

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